

5 **Figure 1: average particle diameters (volume distribution) of precipitated budesonide against temperature, with no sonication.**

BEST AVAILABLE COPY

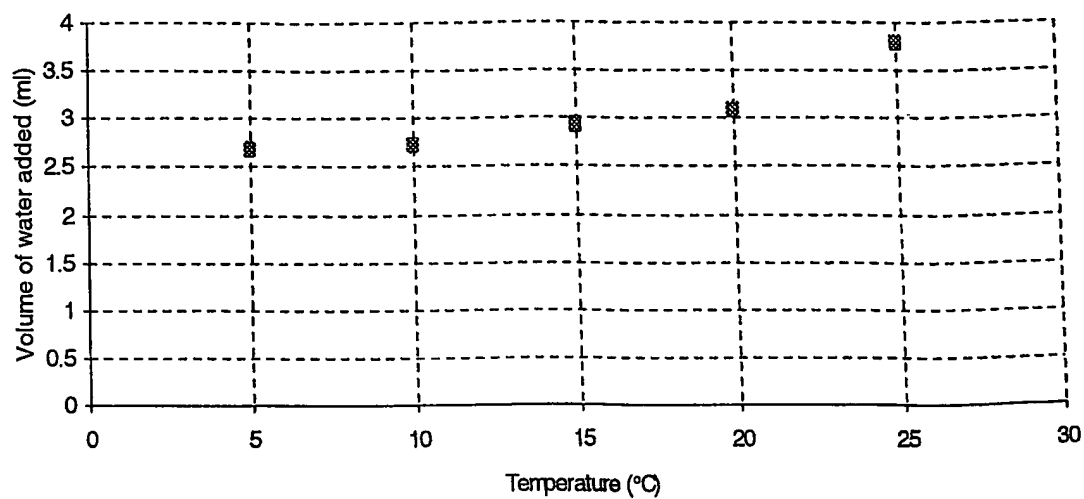


Figure 2: minimal volume of water required to initiate precipitation of budesonide against temperature, with no sonication.

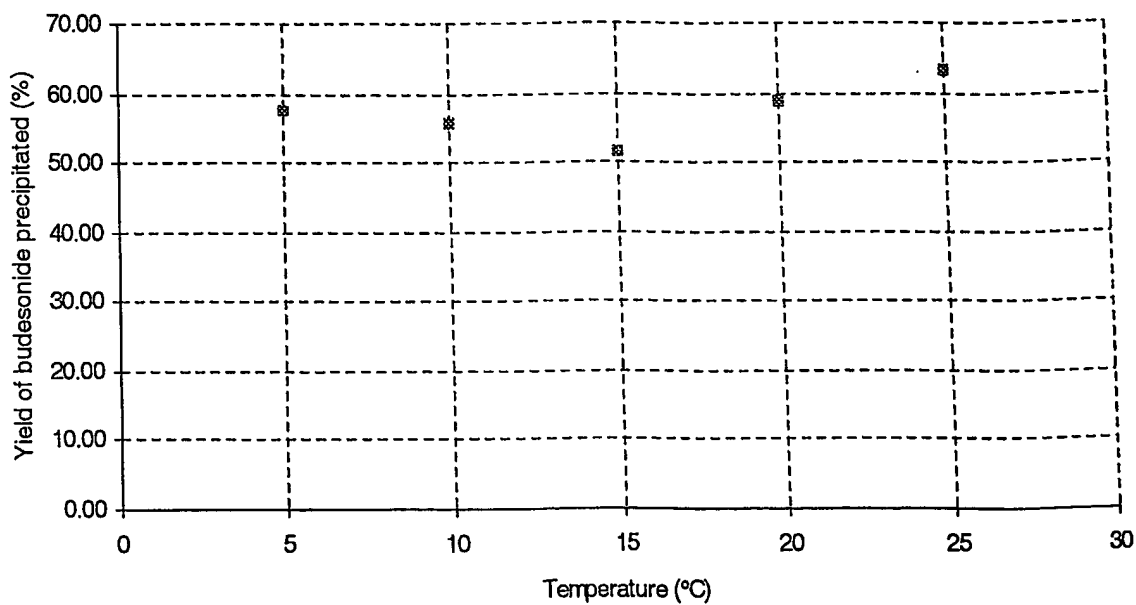
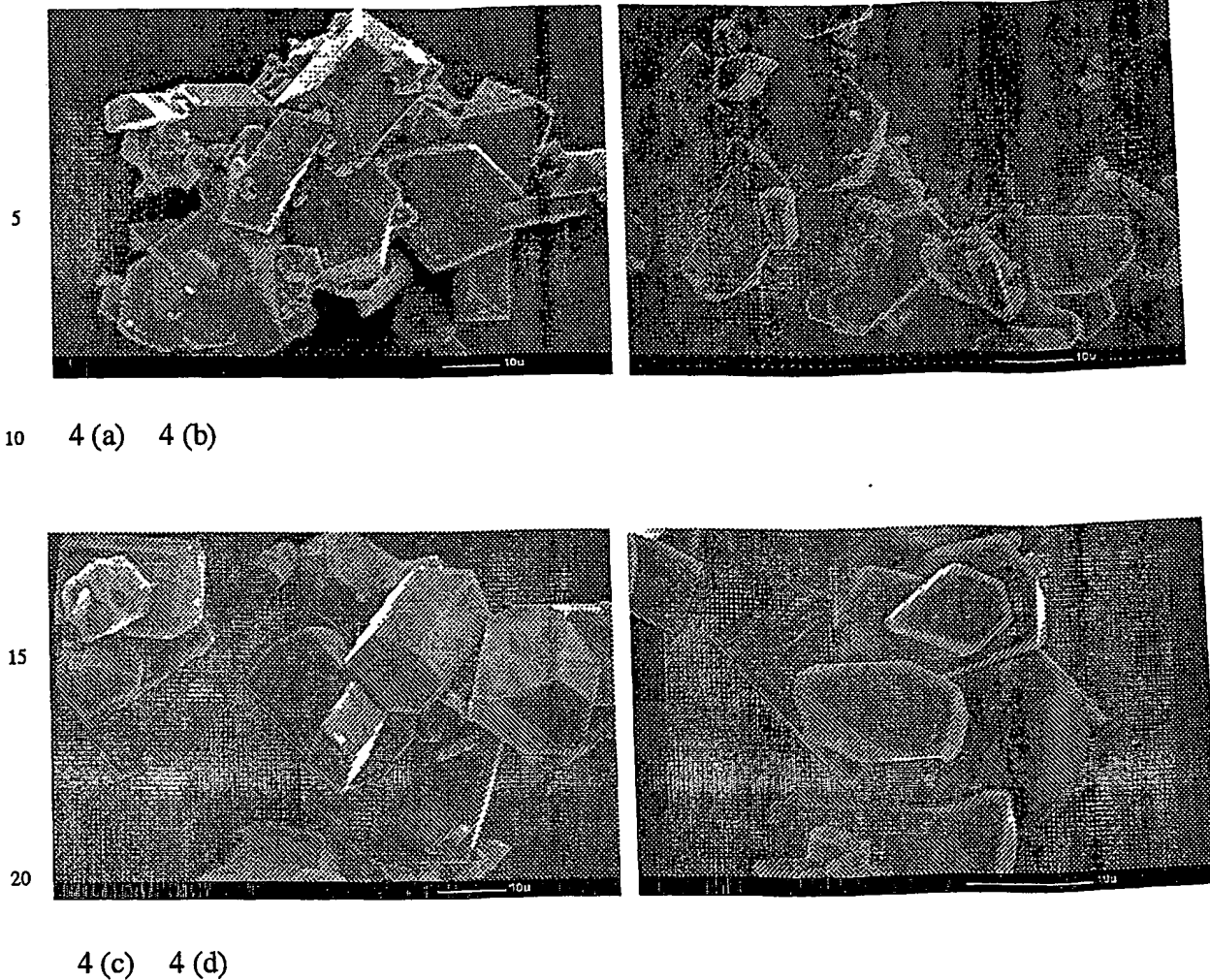


Figure 3: yield of budesonide precipitated against temperature, with no sonication.



25 **Figure 4: SEM pictures of budesonide precipitated without sonication (a) at 25 °C, (b) at 15 °C, (c) 10 °C, (d) 5 °C.**

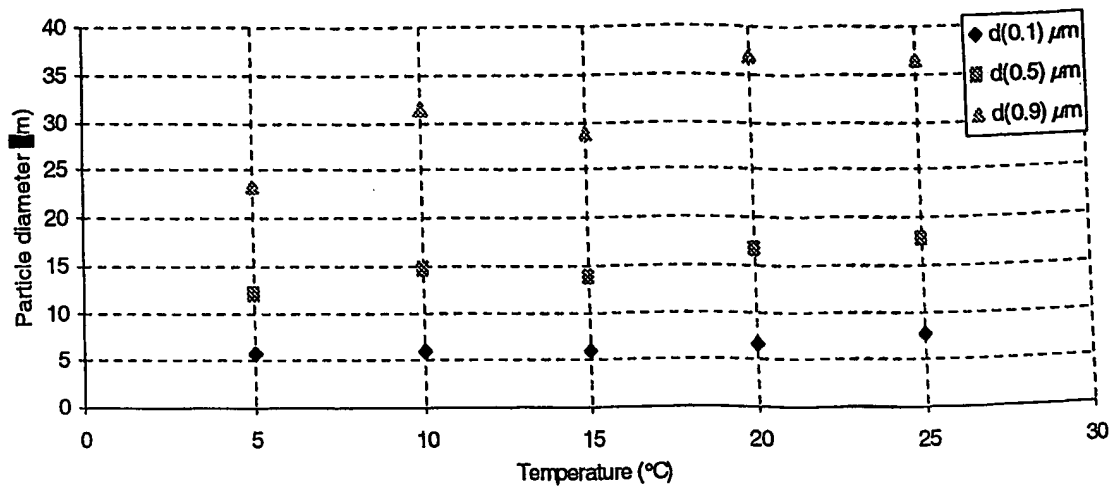


Figure 5: diameters of budesonide particle fully precipitated against temperature, without sonication.

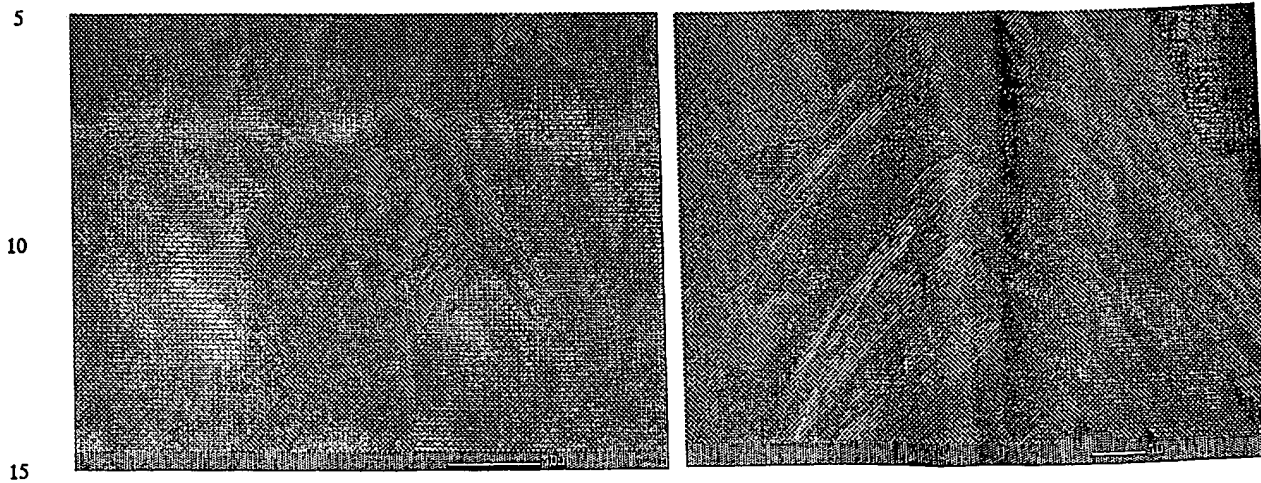


Figure 6: SEM pictures of budesonide fully precipitated without sonication at 15 °C.

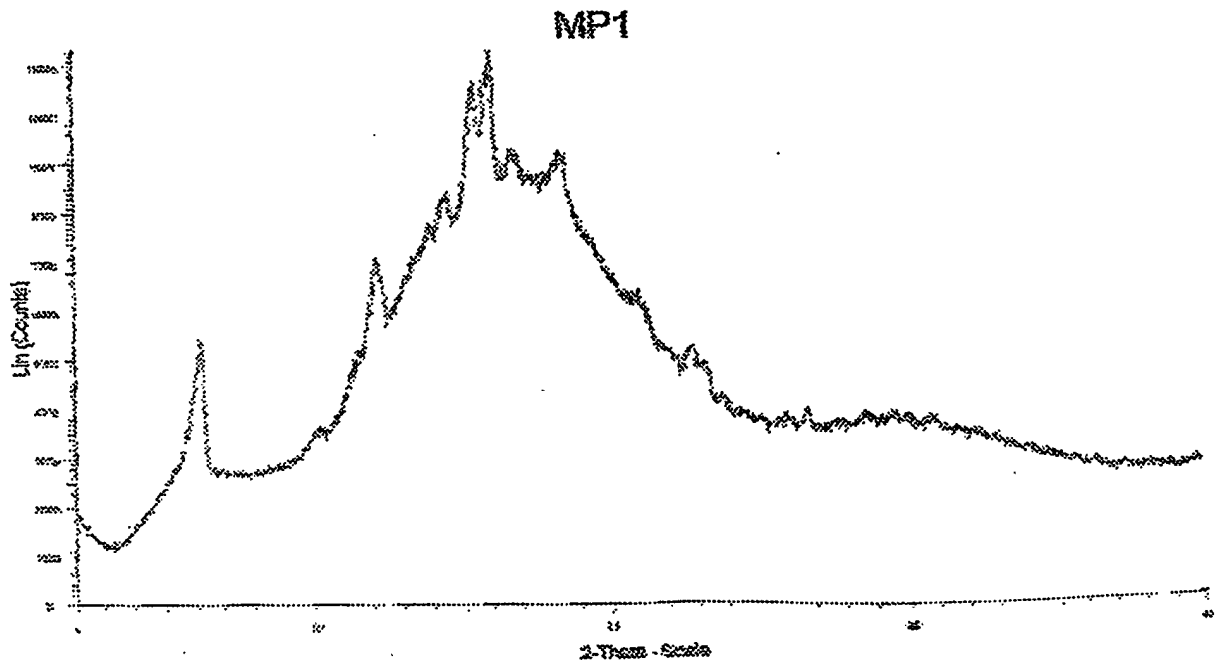


Figure 7: XRPD of budesonide fully precipitated at 15°C without sonication.

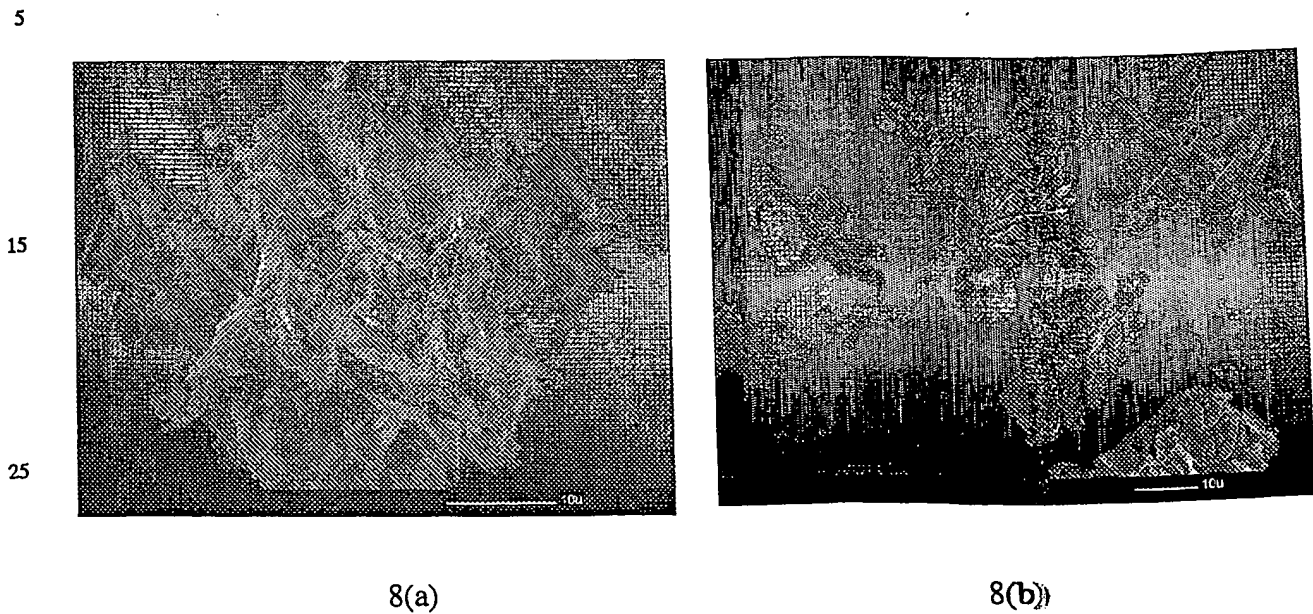


Figure 8: formoterol particles precipitated without sonication at 10 °C.

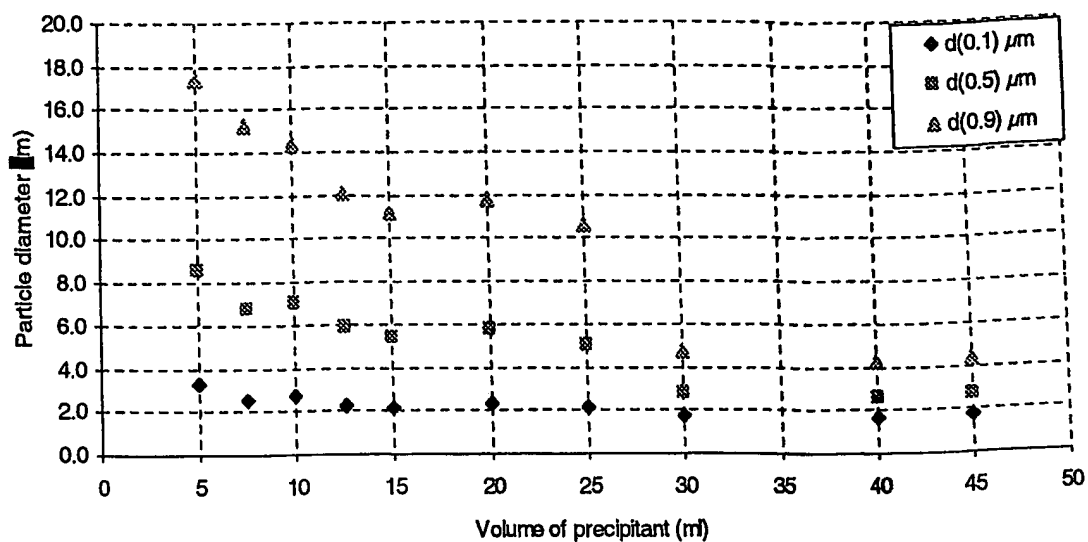


Figure 9: sonocrystallised budesonide particle diameters against volume of precipitant, at 15 °C.

5

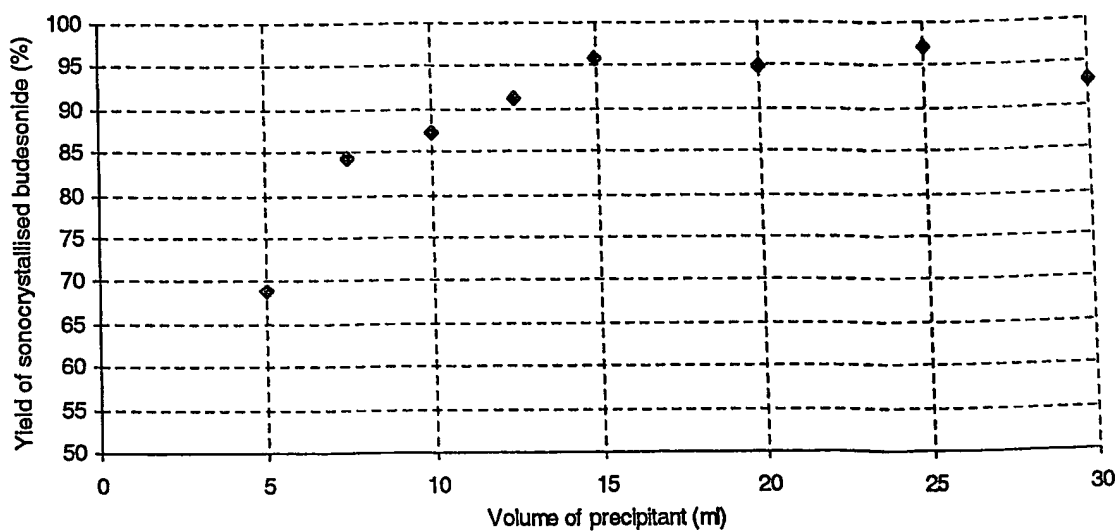


Figure 10: yield of budesonide sonocrystallised against volume of precipitant, at 15 °C..

10

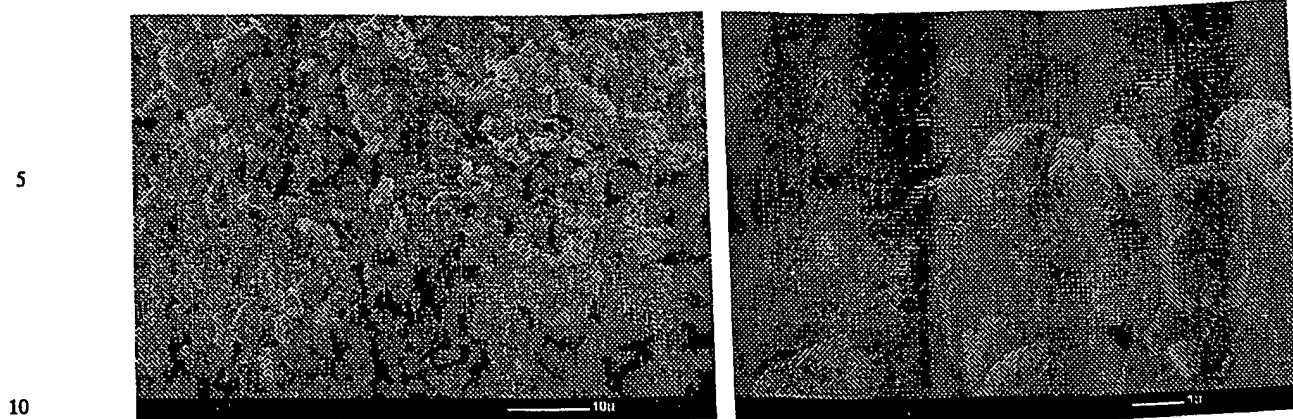


Figure 11: budesonide fully precipitated using 40 ml of water with sonication, at 15 °C.

15

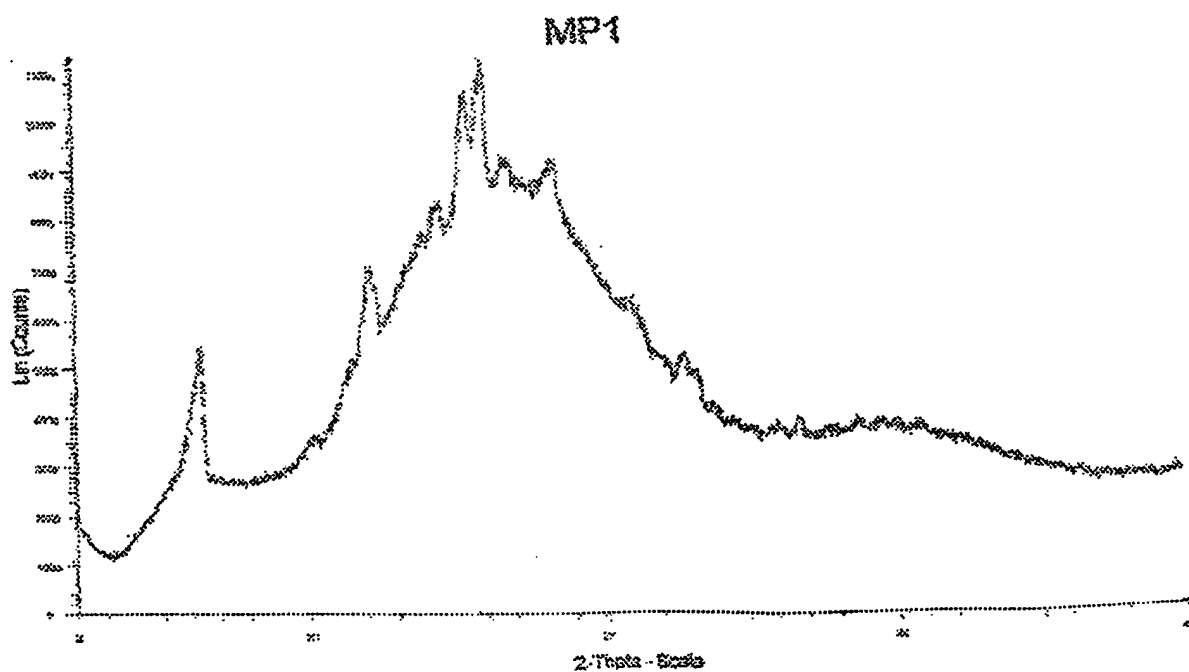


Figure 12: XRPD of fully precipitated budesonide using water with sonication, at 15 °C.

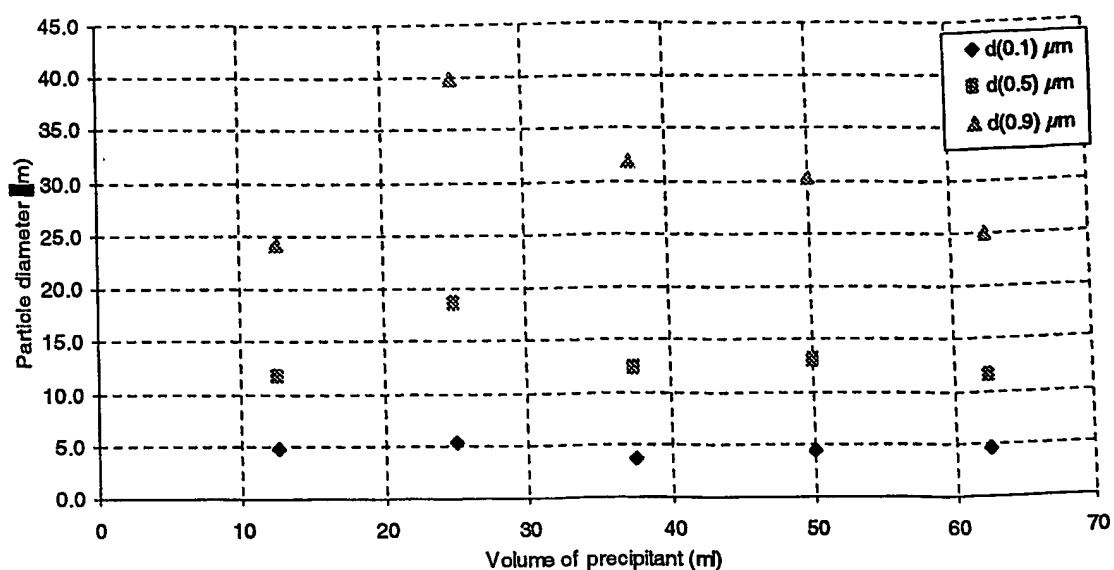


Figure 13: sonocrystallised formoterol particle diameters against the volume of precipitant (acetonitrile) at 15 °C.

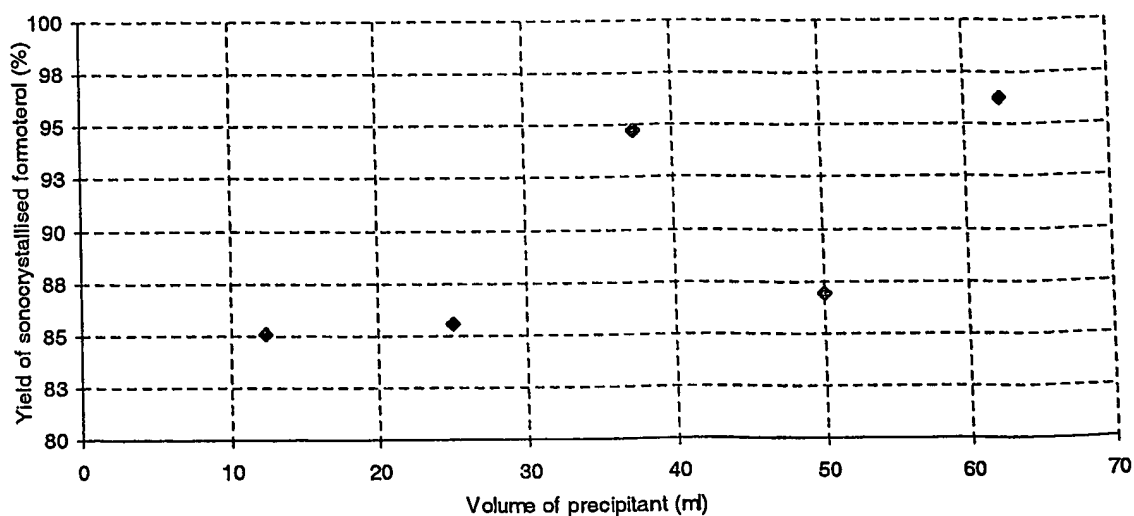


Figure 14: yield of formoterol sonocrystallised against volume of precipitant, at 15 °C.

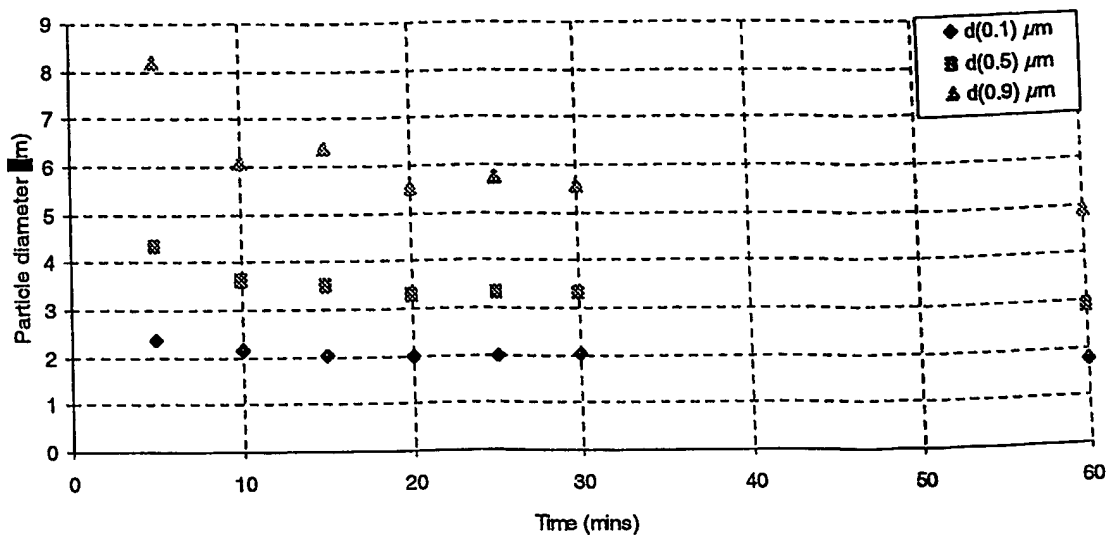


Figure 15: influence of precipitation time on sonocrystallised budesonide particle diameters.

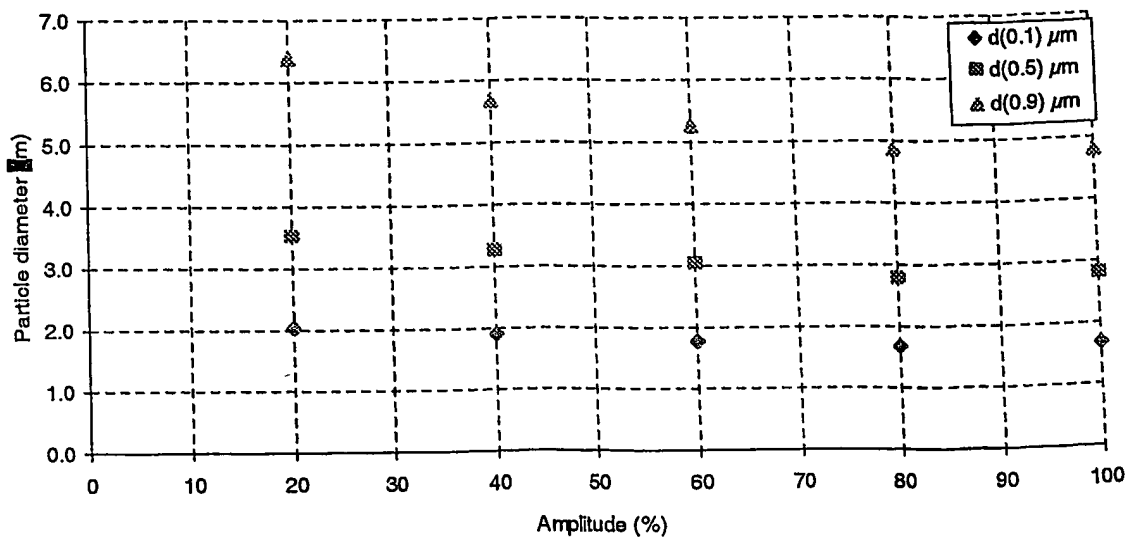


Figure 16: diameter of sonocrystallised budesonide particle against the amplitude of ultrasonic energy.

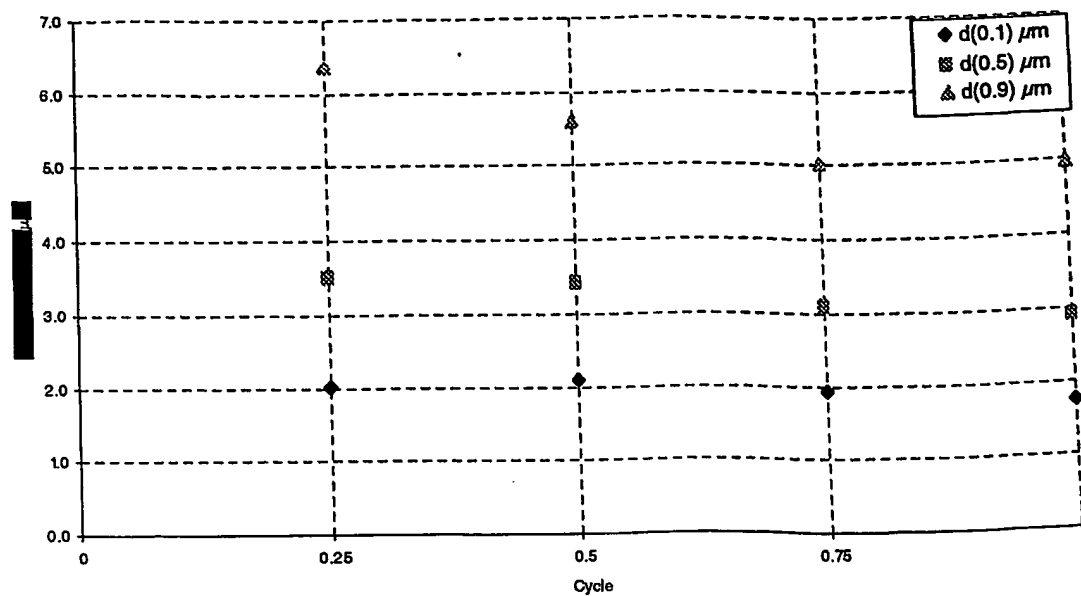


Figure 17: diameters of sonocrystallised budesonide particle against the cycle of ultrasonic energy at 20 % (42 μm) amplitude.

5

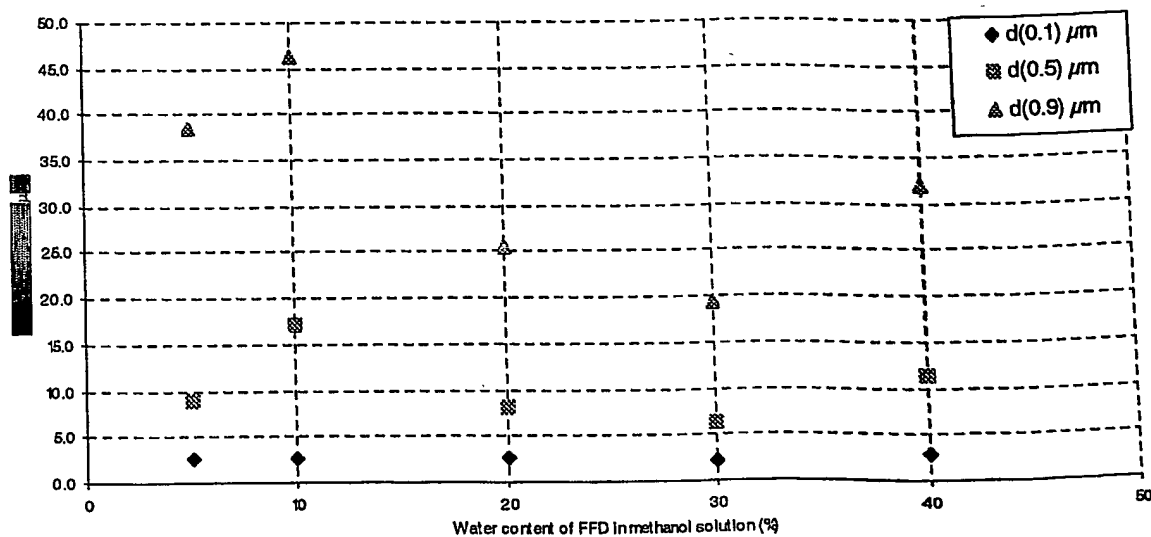


Figure 18: influence of the addition of water on the diameter of sonocrystallised formoterol particles precipitated with diethyl ether.

10

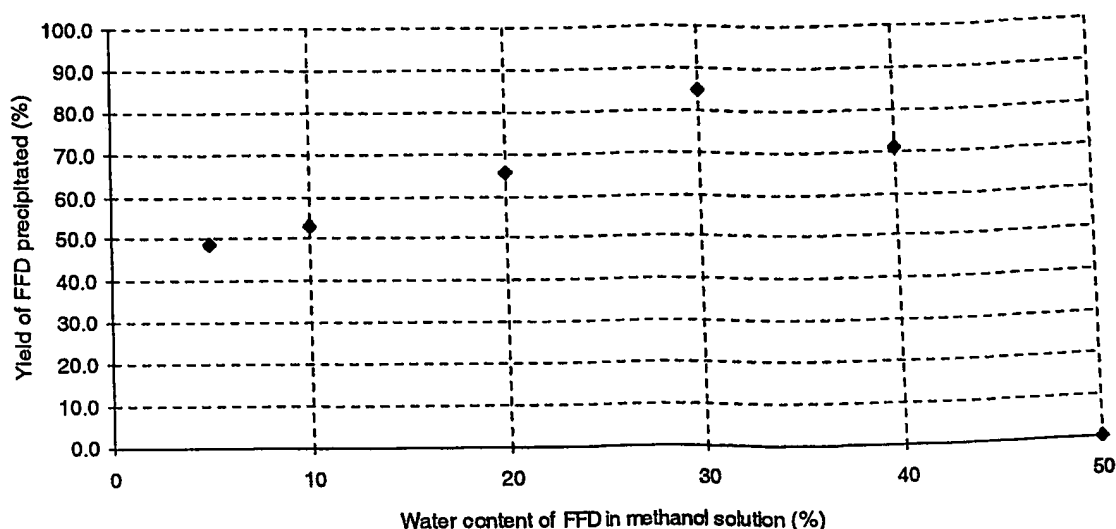


Figure 19: influence of the addition of water on the yield of sonocrystallised formoterol particles precipitated with diethyl ether.

5

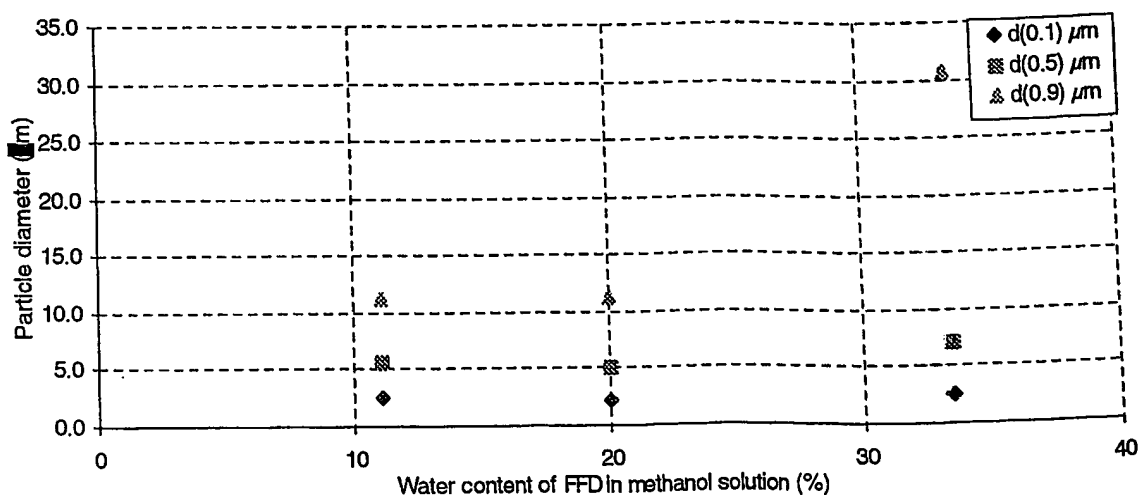


Figure 20: sonocrystallised formoterol particle diameters precipitated with acetonitrile, against the water content of the drug solution

10

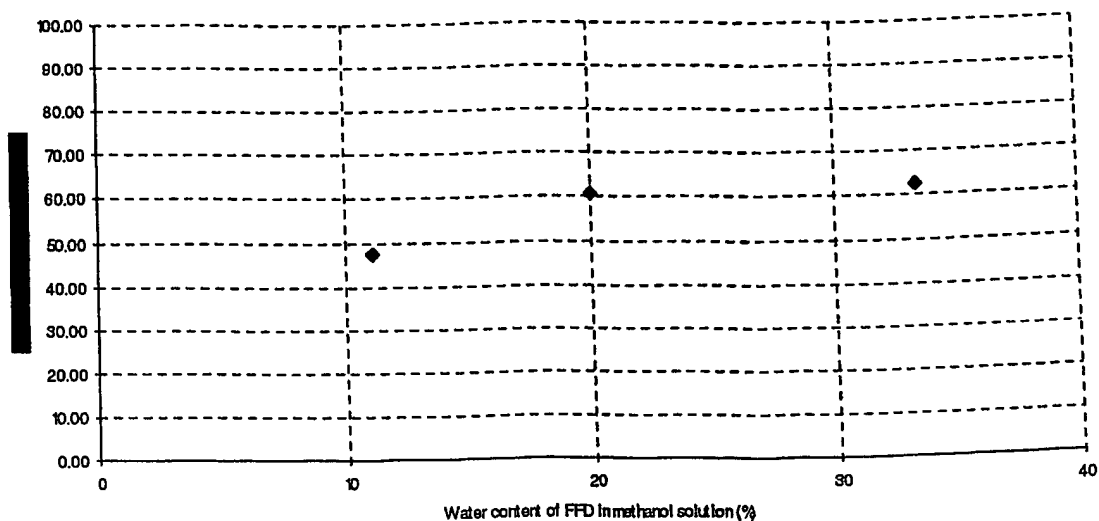
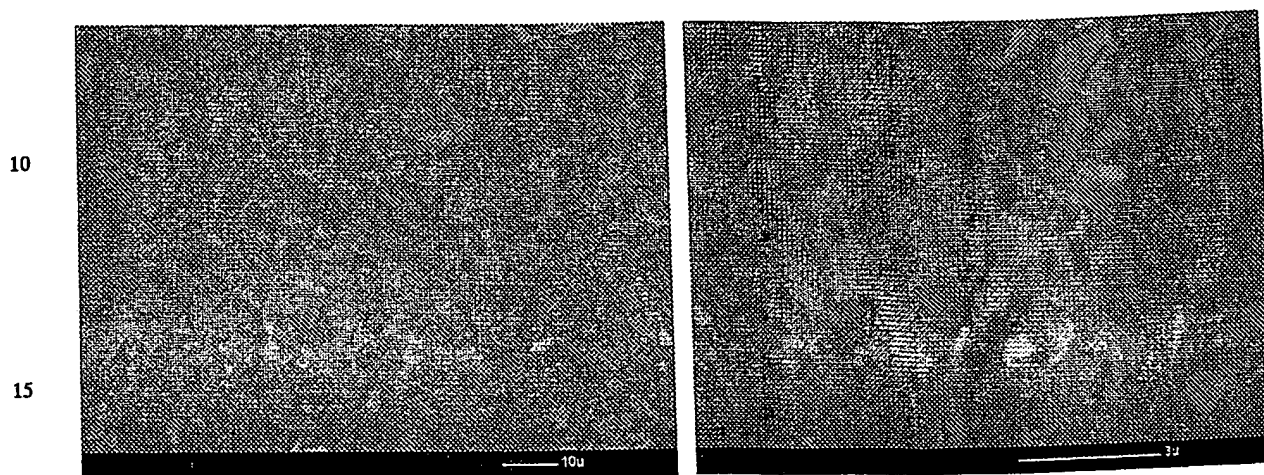


Figure 21: yield of sonocrystallised formoterol particle diameters precipitated using acetonitrile, against the water content of the drug solution.

5



10

15

Figure 22: SEM of formoterol particles precipitated with acetonitrile and sonication, with 20 %w/w water at 5 °C.

20

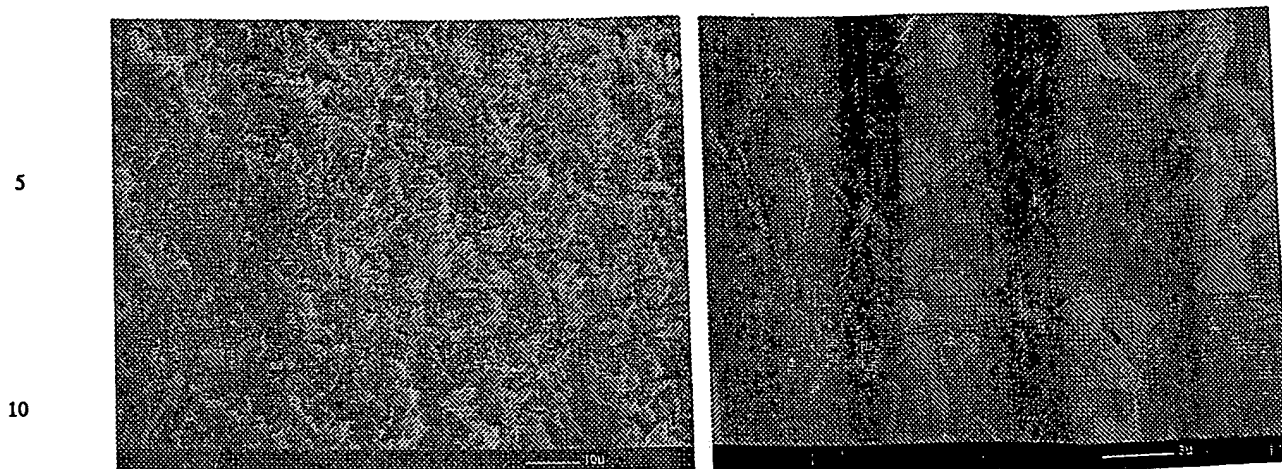


Figure 23: SEM of formoterol particles precipitated with diethyl ether and sonication with 30%w/w water at 15°C.

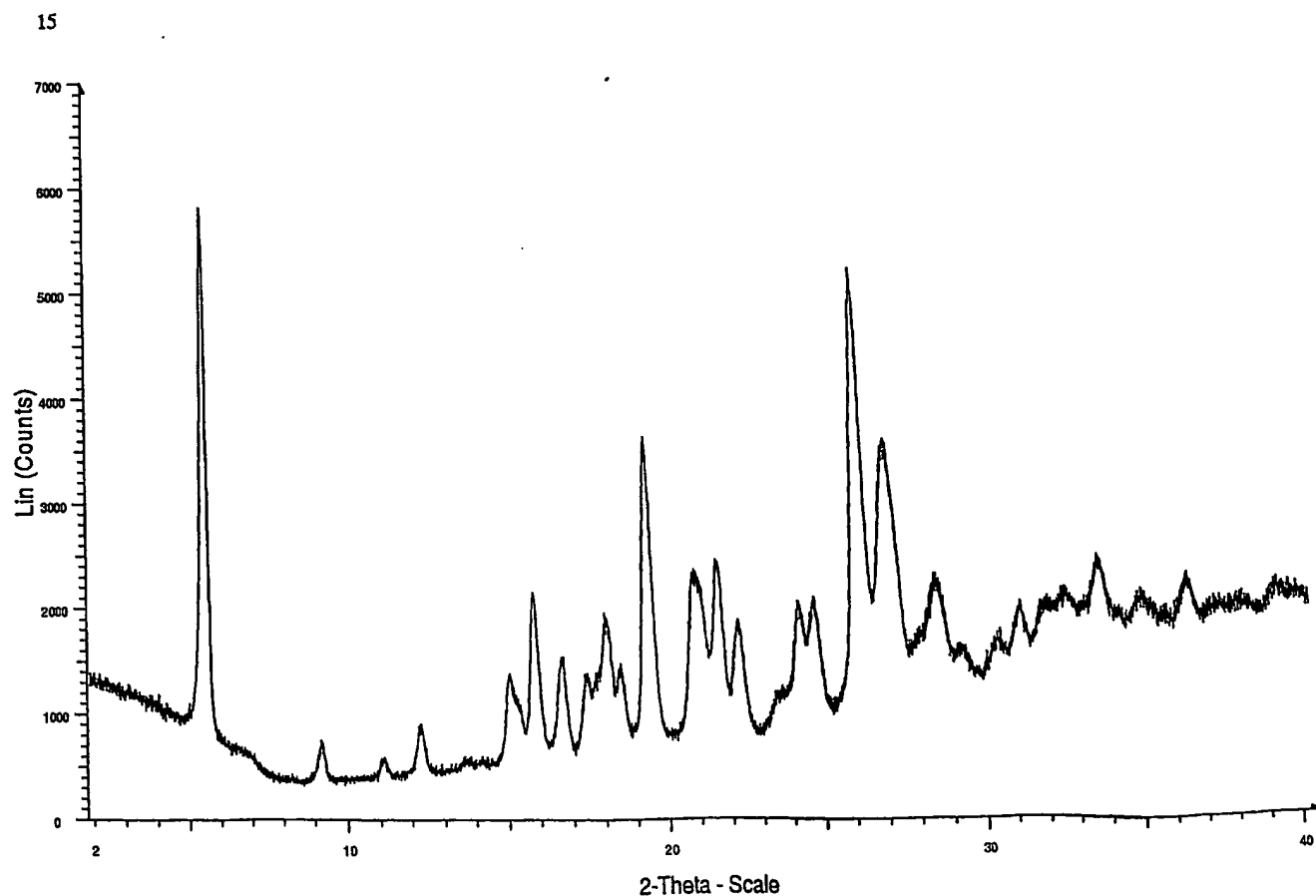


Figure 24: XRPD of sonocrystallised formoterol particles precipitated with diethyl ether from a 30 %w/w water drug solution at 15 °C.

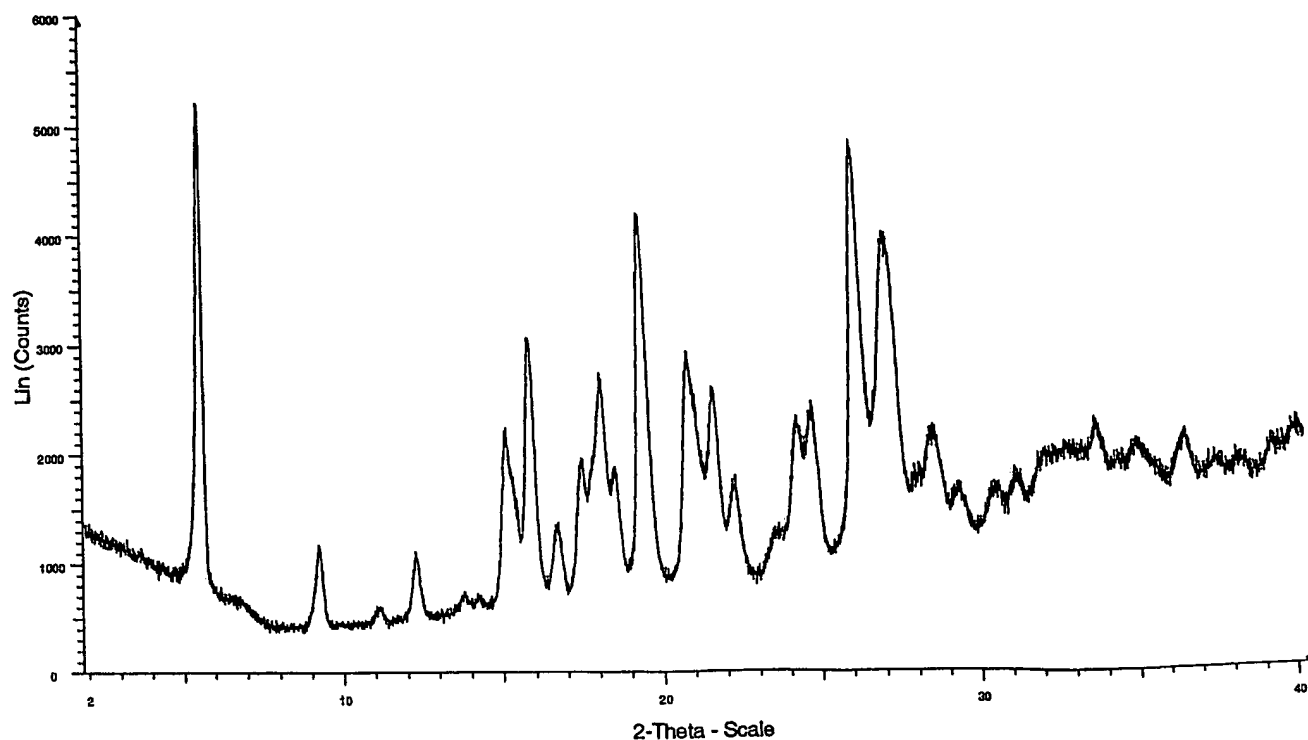


Figure 25: XRPD of sonocrystallised formoterol particles precipitated with acetonitrile
5 **from a 20 %w/w water drug solution at 15 °C.**

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.